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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,483	02/25/2004	Jesus Benavides	ST01024 US CNT	3121

5487 7590 10/21/2005

ROSS J. OEHLER  
AVENTIS PHARMACEUTICALS INC.  
ROUTE 202-206  
MAIL CODE: D303A  
BRIDGEWATER, NJ 08807

EXAMINER
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CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/786,483	BENAVIDES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 5-10, 16 and 18-23 is/are allowed.
- 6) ☐ Claim(s) 1, 2, 4, 15, 17 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/24/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Status of the Application*

This Office Action is in response to applicant's response filed on 8/10/2005.

Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the ground(s) that (1) there is no undue burden of search as evidenced by both inventions being in the same class/subclass, (2) a product and its process should be rejoined, and (3) there was no lack of unity of invention imposed on the corresponding PCT. This is not found persuasive because (1) a search for the product will not always lead to the search for its process even though they are in the same class/subclass, (2) the product and its process will be rejoined should the product be found allowable, and (3) the restriction practices are different than those utilized by WIPO. The requirement is still deemed proper and is therefore made FINAL. Claims 1-24 are pending. Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-10, 15-24 are examined herein.

Claims 3, 5-10, 16, 18-23, directed to a combination of the elected species, 1-[bis(4-chloro-phenyl)methyl]-3-[(3,5-difluorophenyl)-(methylsulfonyl)methylene]azetidine), and a product that activates dopaminergic neurotransmission (bromocriptine, levodopa, ropinirole, pramipexole, rasagiline, and entacapone) has been found allowable.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 16, 18-20, 22, 36 of copending Application No. 10/786,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of formula I in each application is obvious over one another. Both compositions also are comprised of the same product that activates dopaminergic neurotransmission (bromocriptine, levodopa, ropinirole, pramipexole, rasagiline, and entacapone). Moreover, both compositions are used to treat Parkinson's disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 4, 15, 17, 24 are rejected under 35 U.S.C. 103(a) as being obvious over Achard et al. (US 2001/0027193 A1) in view of Ishihara et al. (US 2002/0177593 A1).

The instant claims are directed to a composition comprising a CB1 antagonist of formula I and a product that activates dopaminergic neurotransmission.

Achard et al. teach a CB1 antagonist of the formula I (sections 0001-0033) for use in the treatment of Parkinson's disease (section 0202), however fails to disclose a composition with products that activate dopaminergic neurotransmission.

Art Unit: 1617

Ishihara et al. teach that bromocriptine, levodopa, ropinirole, pramipexole, rasagiline, and entacapone (products that activate dopaminergic neurotransmission) can be used to treat Parkinson's disease (section 0577).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine a CB1 antagonist of formula I taught by Achard et al. with a product that activates dopaminergic neurotransmission taught by Ishihara et al.

A person of ordinary skill in the art would have been motivated to combine a CB1 antagonist with a product that activates dopaminergic neurotransmission because both are taught to treat Parkinson's disease. Concomitant employment of both CB1 antagonist and a product that activates dopaminergic neurotransmission in a method to treat Parkinson's disease would have been reasonably expected to be effective, with at least an additive effect, since both are known to be useful to treat Parkinson's disease separately.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Art Unit: 1617

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

  
SHENGJUN WANG  
PRIMARY EXAMINER